Attachment 4: 510 (k) Summary

NOV 3 0 2004

510(k) Summary

Manufacturer:	Guangzhou Fortunique Ltd. Block B2 Zhou Shan Gang Shi Bei Ind. Ave. Pan Yu District Guangzhou 511410, China
Contact: **Address:**	Jane B. Campbell J. & D. Campbell Associates, Inc. 485 LaRoe Road Chester, New York 10918
Telephone:	(845)469-4289
Fax:	845-469-4212
Email:	jdca@optonline.net
Date Summary Prepared:	May 27, 2004
Product Trade Name:	Guangzhou Fortunique Drapes, Bags and Covers
Common Name:	Equipment drapes, bags and covers
Classification:	II
Predicate Devices:	Medline Band Bags and Equipment Covers K032065 primaGARD Surgical Equipment Covers K022868 Coverall All Equipment Covers Banded Bags & Dome Bags, Various Models, Sterile and Non-sterile K023540 International MedSurge Connections Equipment Covers - K014239 United States Surgical Corporation Equipment Covers K961699 Pinnacle Products Coverall All, Chair Sleeve, Drape-it-All, Tray Sleeve and related products K962288

Description:

Guangzhou Fortunique Drapes, Bags and Covers are made of low density polyethylene film in various sizes and shapes for use in covering equipment. These drapes, bags and covers are offered non-sterile in bulk quantities and sterile in individual packs.

Intended Use:

Guangzhou Fortunique's Drapes, Bags and Covers are intended to cover equipment, to maintain a sterile field and as an aid in the clean up of equipment after surgery or other medical procedures. These drapes, bags and covers are not intended to be used as patient drapes and they have no patient contact.

Fortunique intends to manufacture and market Drapes, Bags and Covers sterile in ready to use form and will also provide them in non-sterile form to other companies for inclusion in convenience packages which they will then sterilize.

Substantial Equivalence:

The Fortunique Drapes, Bags and Covers are substantially equivalent to the predicate devices listed above in that they

- have the same intended use
- are manufactured of the same polyethylene film
- they are offered in the same sizes and configurations
- they have the same physical characteristics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2004

Guangzhou Fortunique, Limited
C/O Ms. Jane B. Campbell
US Agent/Official Correspondent
J. & D. Campbell Associates, Incorporated
485 LaRoe Road
Chester, New York 10918

Re: K041501
Trade/Device Name: Guangzhou Fortunique Drapes, Bags and Covers
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX, MMP
Dated: October 7, 2004
Received: October 8, 2004

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

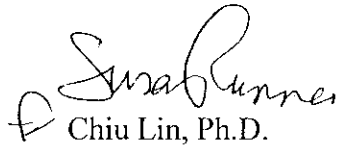
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k): 041501

Device Name: Guangzhou Fortunique Drapes, Bags and Covers

Intended Use: Guangzhou Fortunique's Drapes, Bags and Covers are intended to cover equipment, to maintain a sterile field and as an aid in the clean up of equipment after surgery or other medical procedures. These drapes, bags and covers are not intended to be used as patient drapes and they have no patient contact.

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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041501

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)